

# ***In re Zetia (Ezetimibe) Antitrust Litigation***

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Case No: 2:18-md-2836

## **EPP Class Certification Hearing: Defendants' Presentation on Ascertainability**

*July 7, 2020*

Confidential – Subject to Protective Order

## EPPs Must Establish That the Class Is Ascertainable

- EPPs agree that “ascertainability” is a prerequisite to the certification of a class in the Fourth Circuit. (EPP Memorandum in Support of Class Certification, Dkt. No. 731, at 15.)
- For a class to be ascertainable, there must be an “administratively feasible way” for the court to “readily identify the class members in reference to objective criteria.” *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014).
- A plaintiff must establish ascertainability “by a preponderance of the evidence,” and “a trial court must undertake a rigorous analysis of the evidence to determine if the standard is met.” *Carrera v. Bayer Corp.*, 727 F.3d 300, 306–07 (3d Cir. 2013); *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at \* 6 (E.D. Pa. June 10, 2015).
- In this Circuit, a plaintiff must “**clearly establish** that there is a method by which class membership could be clearly ascertained.” *Harris v. Rainey*, 299 F.R.D. 486, 495 (W.D. Va. 2014) (emphasis added).

## EPPs Must Establish That the Class Is Ascertainable

- A party's “**assurance**” to the court that it “**expects**” to satisfy the requisite elements for class certification is not enough. *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 70 (4th Cir. 1977) (emphasis added).
- Instead, it is incumbent upon the plaintiff to come forward with a methodology for demonstrating ascertainability “**specific to this case**” in order to meet this requirement of Rule 23. *In re Niaspan Antitrust Litig.*, 2020 WL 2933824, at \* (E.D. Pa. June 2, 2020) (emphasis added).
- A plaintiff cannot meet its burden by “merely propos[ing] a method of ascertaining a class without any evidentiary support that the **method will be successful.**” *Carrera*, 727 F.3d at 306; *Vista Healthplan*, 2015 WL 3623005, at \* 6 (emphasis added).
- If identifying class members requires the court to “engag[e] in a **detailed review and analysis**” the ascertainability requirement will not be met. *Dykes v. Portfolio Recovery Assocs., LLC*, 2016 WL 346959, at \*5 (E.D. Va. Jan. 28, 2016) (emphasis added) (denying class certification).

## EPPs Have Not Met Their Burden of Establishing Ascertainability

- EPPs have not proffered an expert on class notice or a PBM expert.
- Instead, EPPs rely *solely* on the following:
  1. The opinions of Laura R. Craft
  2. PBM declarations primarily from other litigations
- Neither is sufficient to satisfy EPPs' burden of showing by a preponderance of the evidence that all class members can be readily identified.

## Craft Provides Only “Assurances” That She “Expects” to be Able to Readily Identify Class Members

- Craft concedes that what she proposes to do is not “standard practice” and she has never done it before:

Craft has never “compile[d] every PBM data source into a single master database” before, which is exactly what she proposes to do here.

5/1/2020 Hr’g Tr. at 112:12-14, 112:18-24

“A: Have I ever collected all of the PBM data necessary to identify all class members in a pharmaceutical class action? No, I have not.”

Craft Dep. at 157:18-20

Craft acknowledges it is not “standard practice to collect *all* prescription data from *all* PBMs for a particular case.”

Craft Rebuttal Decl. ¶ 3

- Craft has not gotten this data in any other case.

Craft has “never been involved in a case where all seven [of the largest] PBMs have all produced their transactional data.”

5/1/2020 Hr’g Tr. at 112:22-24

“Q: In any of the cases described in your CV...have you been provided all the data that you needed to actually run this exercise?

A: ...[T]he answer is no.”

Craft Dep. at 159:7-12

## EPPs Have Not Established Ascertainability With “Evidence Specific To This Case”

- **Craft has not obtained or reviewed PBM data specific to Zetia.**

Craft is "not aware of any" PBM data being produced in this case.

5/1/2020 Hr'g Tr. at 111:15-17

Craft has "not looked at any PBM data which is specific to Zetia and ezetimibe" in forming her opinions in this case.

5/1/2020 Hr'g Tr. at 111:24-25

"I'm not involved in negotiating the production of data" and  
"I have not reviewed data."

Craft Dep. at 105:2-3; 73:11-12

- **Craft concedes that her methodology can be applied in any case.**

"I don't actually need to see the data to know the answer to [the] question."

Craft Dep. at 110:19-21

- **Only one PBM has provided a declaration specific to Zetia.**

## **EPPs Have Not Established That Craft's Methodology For Identifying Class Members "Will Be Successful"**

- 1.** EPPs do not know how many TPPs are in the putative class.
- 2.** EPPs purports to rely entirely on PBM data to identify class members.
- 3.** EPPs ignore significant obstacles associated with obtaining the data Craft claims to need.




## EPPs Do Not Know How Many Putative Class Members There Are

- Although she cannot identify them, Craft posits there are “**approximately 27,802**” TPPs in the class. (Craft Report ¶ 11.)
- But Craft provides no methodology for how she could reconcile various estimates as to the number of TPPs who would be in the class:
  - EPPs suggest there could be as many as **40,000** TPPs based on a “proprietary database.” (EPPs’ Supp. Memo. at 3, Dkt. No. 949.)
  - Dr. Hughes estimates that there could be as many as **2.2 million** TPPs. (Dr. Hughes Hearing Slides at 7, Dkt. No. 940-3.)
- Ultimately, Craft does not know the identity of class members or how many there are because she does not have *any* data to do this analysis.



# Craft Asserts That Class Members Can Be Identified Exclusively Through PBM Data

- In her initial November 15, 2019 declaration, Craft asserts that **four** different data sources can be relied upon to identify class members:

	1 PBM Data	2 TPP Data 	3 Pharmacy Data 	4 Form 5500 Data 
Initial Position	<p>"There are at least three institutional sources of electronic, transaction-specific data for prescription drug sales: pharmacies, PBMs, and the TPPs..."</p> <p>Craft Decl. ¶ 15</p>		<p>"...[I]t is worth noting that the largest retail pharmacies have a parallel set of transaction records containing the same key elements."</p> <p>Craft Decl. ¶ 21</p>	<p>"The Form 5500 data can serve as a cross-check against subpoenaed PBM data."</p> <p>Craft Decl. ¶ 34</p>
Revised Position		<p>"[No] expectation about whether the data that's actually physically in [the Named Plaintiffs'] possession is in any way representative of what's available, i.e., available from the PBM."</p> <p>Craft Dep. at 149:15-20</p>	<p>"There is no need to rely on pharmacy data in this case..."</p> <p>Craft Rebuttal Decl. ¶ 10</p>	<p>"...[Form 5500] data is unnecessary."</p> <p>Craft Rebuttal Decl. ¶ 34</p>

- She now opines that **data from PBMs alone** is sufficient.
- Craft testified that she does not "need the Form 5500 data for ascertainability at all. We use the PBM data . . ." (5/1/2020 Hr'g Tr. at 104:8-9.) 9

## Craft Is Not An Expert on PBM Data

### 1 Craft is a lawyer with an English literature degree

**“Q: And I think we’ve already established that you have a JD degree...And what discipline is your BA in?”**

**A: English literature if you call that a discipline.”**

Craft Dep. at 20:20-21:2  
5/1/2020 Hr’g Tr. at 110:20-111:1

### 2 She has never been employed by a PBM

**“Q: You never worked for a pharmacy benefit manager, correct?”**

**A: That’s true.”**

Craft Dep. at 21:8-10  
5/1/2020 Hr’g Tr. at 111:6-7

### 3 She has not published on PBM data outside litigation

**“Q: But am I correct that there’s nothing specific to PBMs [in the book you published]?”**

**A: I believe you are correct.”**

Craft Dep. at 35:14-24  
5/1/2020 Hr’g Tr. at 111:9

## Mr. Dietz Is An Expert on PBM Business Practices



- Sc.B. in Pharmacy, Duquesne University
- Co-founder of Pharmacy Healthcare Solutions, LLC
- Vice President at Pharmacy Healthcare Solutions, Inc.
- Licensed pharmacist (Pennsylvania)
- Member of several industry organizations, including:
  - National Council of Prescription Drugs Programs (NCPDP)
  - National Association of Chain Drug Stores (NACDS)
  - National Community Pharmacists Association (NCPA)
  - Academy of Managed Care Pharmacy (AMCP)
- Extensive experience in PBM contracting, PBM claims adjudication, PBM formulary placement, and PBM invoicing and pharmacy payments. (Dietz Decl. ¶3.)

## Craft Ignores Significant Obstacles to Identifying Class Members Using PBM Data

1. Data from the top 7 PBMs would not cover all TPPs.
  - *E.g.*, [REDACTED]  
[REDACTED] ( [REDACTED] Dep. at 134-35.)
2. EPPs would need to request information from 40+ PBMs.
  - Craft would require two types of files (1) claims data, and (2) rebate data. (5/1/2020 Hr'g Tr. at 114:11-16.)
  - Each PBM has different data retention policies.
  - Individual contracts may preclude or limit disclosure.

## Craft Ignores Significant Obstacles to Identifying Class Members Using PBM Data

3. Multiple diverse PBM processing platforms would need to be harmonized.
  - Even in harmonizing a much more limited set of non-PBM data Craft made errors. (Errata to Craft Rebuttal Decl., Dkt. No. 913; 5/1/2020 Hr’g Tr. at 92:1-3.)
4. NCPDP standards do not eliminate these issues or ensure that data exists to identify class members.
  - As Mr. Dietz clarified, NCPDP standards are “for data *transmission*” they are “not . . . a standard for data *storage*.” (5/1/2020 Hr’g Tr. at 124:11-17 (emphasis added).)
5. PBMs are likely to resist requests for disclosure of large amounts of confidential claim and rebate data over a five year period.
  - Craft acknowledges that there are many reasons PBMs would resist producing data, including that “it takes some effort” and “they prefer not to open their books.” (5/1/2020 Hr’g Tr. at 91:17-18.)

# Even If It Exists, Craft Ignores That Obtaining PBM Data Will Require Substantial Litigation

- Express Scripts vigorously resisted producing data *Opana ER Antitrust Litigation*

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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION	
IN RE OPANA ER ANTITRUST LITIGATION	MDL No. 2580 Lead Case No. 14-cv-10150 Hon. Harry D. Leinenweber
THIS DOCUMENT RELATES TO:	
All Actions	

**NON-PARTY EXPRESS SCRIPTS HOLDING COMPANY'S OPPOSITION TO  
END-PAYOR PLAINTIFFS' MOTION TO COMPEL NON-PARTY  
EXPRESS SCRIPTS TO COMPLY WITH PLAINTIFFS'  
OCTOBER 12, 2018 DOCUMENT SUBPOENA**

Non-Party Express Scripts Holding Company ("Express Scripts") opposes End-Payor Plaintiffs' ("EPPs") motion to compel compliance with a third-party document subpoena dated October 12, 2018 ("Subpoena") in connection with the underlying action *In re Opana ER Antitrust Litig.*, No. 1:14-cv-10150 (N.D. Ill.) (Leinenweber, J.). The Subpoena demands 29 overbroad categories of documents for the time period of January 1, 2008 through December 31, 2017, seeking information, among other matters, related to prescription claims for opiate medicines used to treat moderate to severe long-acting pain ("Long-Acting Opioids"), such as Opana ER. *See Mot. to Compel*, Ex. A.<sup>1</sup> This Court should deny EPPs' motion to compel on five independent grounds, each of which is sufficient for denial.

"EPPs essentially request that Express Scripts gather and produce an ***inordinate amount of data, and perform quasi-expert services***, to aid EPPs in their motion for class certification. Express Scripts, as a non-party, has no obligation to undertake such a burden. EPPs have not identified, and Express Scripts is not aware of, any case that requires a non-party to produce ***reams of sensitive, proprietary client information*** to aid a party in its efforts to ascertain class members." (Br. at 9 (emphasis added).)

Express Scripts claimed that "EPPs acted in bad faith, by attempting to leverage the burden of producing voluminous data responsive to overly broad and unreasonable document requests, to improperly force non-party Express Scripts into producing a declaration." (Br. at 15.)



## The PBM Declarations Do Not Establish That Class Members Can Feasibly Be Identified Using PBM Data

- Declarations from PBM representatives from other cases are insufficient to meet EPPs' burden of establishing ascertainability with evidence "specific to this case." *In re Niaspan Antitrust Litig.*, 2020 WL 2933824.
- Nor are they admissible evidence in this proceeding:

"With respect to Plaintiff's citation to a declaration in another case, documents filed in other cases are of no assistance to Plaintiff, as the Court cannot take judicial notice of the truth of facts set forth in filings in other cases."

*Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001).
- Even if they were, none of them address whether those PBMs have data concerning Zetia / ezetimibe for the entire class period.
- Even if they did, EPPs have not produced declarations for 3 of the top 7 PBMs, much less from any of the smaller PBMs.

## EPPs' Multiple Class Exclusions Require "Detailed Review and Analysis" to Assess Class Membership

- EPPs' class definition has **11 exclusions**. Among them are:
  - Federal/state government plans except cities, towns, municipalities, or counties with self-funded plans.
  - Fully-insured insurance plans.
  - Plans that used Optum as their PBM.
  - Emblem Part D Plans.
- EPPs offer no evidence that the PBM data Craft surmises exists will allow these exclusions to be applied and Craft provides no methodology to apply those exclusions.
- Applying such exclusions requires a "complicated and individualized process" that renders the class not **ascertainable**. See *Spotswood v. Hertz Corp.*, 2019 WL 498822 at \*6 (D. Md. Feb. 7, 2019); *Vista Healthplan*, 2015 WL 3623005, at \*11.
- Even if it is theoretically possible, this individualized process needed to apply these exclusions and identify class members "would be prohibitively expensive and thus infeasible." *In re Niaspan Antitrust Litig.*, 2020 WL 2933824 (estimating that process identified by EPPs could cost up to \$18 million).



# Craft Ignores the Complexity and Individual Analysis Needed to Exclude Non-Class Members

1

More than 10,000 government plans may meet the proposed class definition and each will need to be individually analyzed. (Dietz Decl. ¶ 78.)

- Craft fails to acknowledge that she will need to analyze each one in order to **exclude** federal and state entities and **include** local and municipality entities.
- Craft admits that this analysis cannot be done based on plan names, so one would need to “separately ask” the PBMs to create a file. (Craft Dep. at 165-166.)

2

There are more than 10,000 plans where the funding type (self-funded vs. fully insured) cannot be easily determined from PBM data. (Dietz Decl. ¶ 66.)

- Craft admits that PBM data is not “required” to identify whether a plan is fully insured. (Craft Dep. at 193.)
- Instead, Craft initially stated that plan funding can be determined by “health plan IDs” and “group IDs” available on pharmacy ID cards.
- Her new reliance on BIN/IIN and PCN numbers from the NCPDP guidelines does not allow her to distinguish between plans with different funding arrangements.

3

There are more than 4,000 mixed-funded plans for which Craft’s opinion does not account. (Dietz Decl. ¶ 60.)

## Craft Ignores the Complexity and Individual Analysis Needed to Exclude Non-Class Members

- 4 OptumRx's acquisition of multiple PBMs during the proposed class period requires individual analysis. (Hughes Supp. Decl. ¶ 20, Fig. 1.)
  - The carve-out of Optum TPPs injects questions as to whether clients of the entities acquired by Optum (e.g., [REDACTED]) are excluded. (*Id.* ¶ 20.)
  - This exclusion requires highly individualized analysis of multiple data sources in order to identify which TPPs had Optum as their PBM and for what time periods. (*Id.*)
  - Craft's only response is that the identity of the PBM is an "indelible field in the data" but she cites nothing for that proposition and it is not among the NCPDP fields she identifies as standard. (Craft Supp. Decl. ¶ 38; Craft Decl. ¶ 27.)
- 5 Emblem's partnership with the City of New York requires detailed analysis with respect to class membership (Hughes Supp. Decl. ¶ 22.)
  - In light of the proposed exclusion of Emblem, complex individualized analysis would need to be undertaken to determine if TPPs that switched to Emblem as a result of this partnership are included or excluded from the class and for what time period. (*Id.*)
  - Craft claims that she can perform this analysis by a "straightforward data query," but does not identify the data to be queried or whether it is available. (Craft Supp. Decl. ¶ 39.)

## *Niaspan*: Background and Holding

- EPPs sought certification of a class in reverse payment case involving Niaspan.
  - EPPs' Experts: Myron Winkelman (PBM); Eric Miller (notice administration); *Laura Craft* (pharmaceutical industry data).
  - Defendants' Expert: *Donald Dietz* (PBM and pharmacy industry and data).
- The court concluded that "EPPs have failed to carry their burden of showing a reliable and administratively feasible mechanism for identifying class members by a preponderance of the evidence."

*In re Niaspan Antitrust Litig.*, 2020 WL 2933824.

## Niaspan: The Court's Reasoning

- EPPs faced an “uphill battle” given their “complex class definition with multiple exclusions.”
- Craft’s assertion that she could “merge the data from various sources, identify and eliminate data errors, transform the data to standardize fields, eliminate duplicates, and compile a list of reflecting a list of class members”:
  - “[D]oes not offer a methodology specific to this case.”
  - Does not permit defendants to “meaningfully test the reliability of EPPs’ proposed method of identifying class members.”
- Instead, Craft provided “mere assurances” and “*ipse dixit*” that are insufficient “to prevail under a rigorous ascertainability analysis.”
- Such an “ad hoc approach to applying class exclusions and the lack of a comprehensive methodology for systematically applying exclusions” does not satisfy Rule 23.
- Even if Craft’s methodology were “technically possible” the court was “concerned...EPPs’ proposed methodology would be prohibitively expensive.”

# EPPs' Proposed Class is Even More Complex Than *Niaspan*

	Zetia	Niaspan
Proposed Class Members	Third Party Payors (TPPs)	Individual consumers
Proposed Class Exclusions	Federal and state government entities	
	Fully insured health plans	
	PBMs	
	Optum Health Part D plans	Brand-only purchasers after Sep. 2013
	Silverscript Part D plans	Flat co-payers
	Humana Part D      Emblem Part D	
	Optum Health Managed Care Plans	
	TPPs with OptumRx as PBM	

## EPPs' Ascertainability Evidence Is Even Weaker Than *Niaspan*

- No PBM or notice expert proffered.
- No evidence concerning use of pharmacy data or TPP data to supplement PBM data.
- Only one Zetia-specific PBM declaration.

# Craft's Methodology Suffers From The Same Flaws That Doomed The EPP Class In *Niaspan*

## Zetia

"If this data is obtained from multiple PBMs through subpoenas, **OnPoint would be able to merge the data, identify and eliminate data errors, transform the data to standardize fields, eliminate duplicates (if any), and compile a list reflecting the identities of the Class members contained in the data...** This process is manageable and can be carried out programmatically, despite the fact that the data would be obtained from multiple sources." (Craft Declaration, ¶ 6, emphasis added)

## Niaspan

"Craft's six-step methodology that '**OnPoint would be able to merge the data from the various sources, identify and eliminate data errors, transform the data to standardize the fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data...**' does not offer a methodology 'specific to this case.'" *In re Niaspan Antitrust Litig.*, 2020 WL 2933824 (internal citations omitted, emphasis added)

**"Without more information about the process** through which Craft claims she will 'compile a list reflecting the identities of the class members,' **defendants lack the ability to meaningfully test the reliability of EPPs' proposed method of identifying class members.**" *In re Niaspan Antitrust Litig.*, 2020 WL 2933824 (internal citations omitted, emphasis added)

## None of the Cases EPPs Cite Have Found Ascertainability Based on Craft's Opinions or Methodology

Case	PBM Expert	Data Sources Relied Upon
In re Suboxone Antitrust Litigation (E.D. Pa.)	Myron Winkelman	<ul style="list-style-type: none"> <li>• Top 6 PBMs</li> <li>• Largest 10 TPPs</li> <li>• Top 10 chain store pharmacies</li> <li>• Top 5 mail order pharmacies</li> </ul>
In re Loestrin 24 FE Antitrust Litigation (D.R.I.)	Myron Winkelman	<ul style="list-style-type: none"> <li>• PBMs</li> <li>• State insurance commissioners</li> <li>• IRS Form 5500s</li> </ul>
In re Solodyn Antitrust Litigation (D. Mass.)	Paul DeBree	<ul style="list-style-type: none"> <li>• Multiple data sources</li> </ul>
In re Nexium Antitrust Litigation (D. Mass.)	<i>Court did not analyze ascertainability.</i>	
In re Lidoderm Antitrust Litigation (N.D. Cal.)	<i>In the Ninth Circuit, "ascertainability . . . is not a requirement under Rule 23."</i>	
In re Restasis Antitrust Litigation (E.D.N.Y.)	<i>Applied the Second Circuit's "modest threshold" standard, which is inapplicable here.</i>	